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December 22, 1999

Documents Management Branch
HFA-305, Room 1061
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20853

Re: Docket No. 99N-4491
FDA's Proposed Strategy on Reuse of Single Use Devices

Dear Sir or Madam:

This letter presents ECRI's written comments on FDA's Proposed Strategy on Reuse of Single Use Devices (SUDs). These comments detail those from my oral presentation at the FDA open meeting on reuse of single-use devices held on December 14, 1999. We present here comments on three specific areas of the proposed strategy:

1. Difficulties in developing risk categories and applying regulations to types of devices.

2. Regulation of healthcare providers as original equipment manufacturers (OEMs) or third-party reprocessors.

3. Regulation of physicians' offices in addition to healthcare facilities.

Background

ECRI has a long-standing and marked interest in the reuse of single-use medical devices. As an independent, nonprofit health services research organization ECRI has maintained a mission to protect the public from unsafe, ineffective, and costly medical technologies and related practices. In our 30-year history, we have investigated tens of thousands of medical device related accidents, injuries, and deaths and have provided in-depth technical and intellectual resources for medical technology decision makers.

Reuse of single-use medical devices is but one topic on which healthcare organizations have sought ECRI guidance. In our extensive 1997 monograph on reuse (copy available upon request), ECRI concluded that there is no clear evidence that reuse of single-use medical devices is either safe or unsafe for patients. We believe that conclusion stands today. We also concluded that safe, effective, and properly documented reprocessing of a single-use device would likely be a daunting task for users themselves (e.g., hospitals, surgicenters, clinics, physicians' offices, nursing homes).

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The reuse of SUDs undeniably carries with it a number of *potential* risks related to infection, materials degradation, and compromised device performance. The recent debates have bantered around anecdotal examples of a few incidents involving a limited number of device types and an even more limited number of specific makes and models of SUDs. At the AAMI/FDA conference of the reuse of single-use devices in May 1999, I presented ECRI's analysis of the FDA databases and the medical literature related to reported problems with reuse and published studies of reuse safety and efficacy. Despite approximately twenty years of reuse, there is a dearth of evidence of actual incidents of patient injuries or deaths. This contrasts starkly against the backdrop of tens of thousands of deaths annually from medical errors that have received much recent attention and suggests a rethinking of regulatory priorities and application of limited FDA resources.

Risk Categories and Types of Devices

The mantras of the various encampments in this debate have been either "Prove that reuse is safe" or "Prove that reuse is unsafe." For the risk categories being proposed, or for specific types of single-use devices, the issue should not be simply "Show me the data." This is too narrow a view. For SUDs, device designs and materials change too frequently to be able to apply broad regulations to devices based on general type or on categories of risk. ECRI believes that, in practice, it will be unduly cumbersome and ineffective for FDA to classify SUDs by either risk category or to apply regulations by device type. As we disclosed in our *Special Report on Reuse*, the subtle differences in design and materials of SUDs dictate that risk analysis be done on a model-by-model basis. It is likely that some types of devices will straddle multiple risk categories, and even this will change as OEMs modify materials and device designs, further complicating the classification strategy.

Consider, for example, disposable endotracheal tubes (21 CFR 868.5730, Class II) that are on FDA's draft list of devices suspected of being frequently reused. Disposable tracheal tubes can be smooth PVC plastic that may be relatively easy to clean and effectively sterilize. But they may also be of a laser ignition resistant design, made of a helical metal sheath having complex crevices in the coil junctions that would be difficult or impossible to effectively clean. Both tubes are disposable. Both are classified by FDA as the same type of device. But they are vastly different in their ability to be effectively reprocessed after use. A model-by-model risk analysis of reprocessing is therefore needed for any risk classification scheme considered within FDA's regulatory models.

Although broad categories of SUD types may be able to be generally categorized related to "low-risk", "moderate-risk", or "high-risk", the approval process for the low- and moderate-risk categories will nonetheless require a model-specific approval process. Further, any meaningful risk analysis for a general type of SUD must compare data for the incidence of complications, serious injury, or death for that type of reused SUD to these same complications from *non-reused* SUDs and from *reusable* devices of the same device type. As such, the analysis must go beyond determining denominator data for incidence of use of single-use products.

Regulation of Healthcare Providers as OEMs and Third-Party Reprocessors

Some degree of regulation or accreditation oversight is warranted to help ensure that the current level of reuse, or a future increase in reuse, does not pose unacceptable risks to patients. However, ECRI disagrees with the proposed FDA approach to regulate healthcare organizations in the *same manner* as OEMs and third-party reprocessors. To impose the same regulatory requirements on healthcare organizations is inappropriate and unreasonable. FDA recognizes that such regulations would impose upon healthcare providers an additional regulatory burden that they are ill equipped to comply with. FDA has also recognized that hospitals must already answer to state licensing boards, the Health Care Financing Administration, and a variety of other regulatory bodies. If providers are regulated as OEMs or third-party reprocessors, we foresee three likely outcomes:

1. All reuse will shift to third-party reprocessors, driving healthcare costs up.

2. Reuse will stop altogether, and the purchase of more expensive single-use devices will escalate, significantly driving up the cost of healthcare, possibly depriving some patients access to effective treatment modalities.

3. The practice of reuse will be driven underground, once again, which will discourage open exchange of information and experience regarding reuse and make surveillance of the practice impossible.

An additional layer of FDA regulatory oversight, if truly to be considered for application to healthcare providers, must be seriously weighed against the potential benefit to the public, to the costs of FDA implementation, and against any evidence of significant risk to patients from reuse.

Regulation of Physicians' Offices in Addition to Healthcare Facilities

Reuse of single-use devices is an activity conducted by the providers of healthcare as a subset of their business activities directed at caring for the ill. The consideration to regulate reuse by hospitals is just as much an intrusion into the practice of medicine by a healthcare facility as would be a proposal to apply these regulations to a private physician's office. The regulation of the physician office practice is an issue that the debate on reuse has, so far, delicately skirted. The FDA and Congress have always maintained that they do not claim an authority to interfere with a physician's practice of medicine in his or her provision of patient care. Witness the exemption of physician private practices from the requirements of FDA's MedWatch medical device problem reporting regulations.

Today, in many physicians' offices a range of procedures and services are performed that rival care given at surgicenters and hospital outpatient clinics. As brief examples, in vitro fertilization and cystoscopy are both now commonly performed in a private physician's office, with the same complement of single-use instruments and devices used in the hospital or surgicenter and with the same potential risks of infection or device failure from reprocessing of those single-use products. Unlike the issues of device problem reporting, which are several steps removed from having a direct impact on patients, it is being argued in this instance that reuse of single-use disposables has a direct impact on patient safety and outcomes. If you are to argue that reuse is a hazard with risks sufficient to warrant FDA regulation of healthcare facilities, then that same logic inescapably applies to the private physician's office. As such, regulation of the physician practice that reuses single-use devices must be considered equally with regulation of a healthcare facility that engages in this practice.

The practice of reuse therefore poses an inevitable course of action of direct FDA regulation of the private physician practitioner. This must apply to all facets of the proposed regulations related to enforcement timing, audits/inspections, mandatory FDA registration, and data submission.

In lieu of direct FDA regulation of healthcare facilities and physicians offices, it has been recognized by FDA, in item No. 1 of it's proposed strategy, that FDA would consider "collaborating with accredited third-party organizations...to ensure that the reprocessing operations are being performed in accordance with the agency's requirements." Third-party organizations such as the American Hospital Association, the Joint Commission on Accreditation of Healthcare Organizations, and the American Medical Association are appropriate candidates for FDA to collaborate with in this regard.

Questions about our comments and requests from regulators for a complimentary copy of our reuse monograph may be directed to me at ECRI, (610) 825-6000, ext. 5223.

Sincerely,

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Enclosures

cc: Joel J. Nobel, M.D., President, ECRI

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